US HOUSE OF REPRESENTATIVES

HOUSE COMMITTEE ON PUBLIC WORKS AND TRANSPORTATION

SUBCOMMITTEE ON PUBLIC BUILDINGS AND GROUNDS

TESTIMONY OF DR. GIO BATTA GORI

ON H.R. 881: LEGISLATION TO BAN SMOKING IN FEDERALLY OWNED AND LEASED BUILDINGS

APRIL 22, 1993

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Mr Chairman, Members of the Subcommittee.

I am Dr. Gio Batta Gori. I will not restate my qualifications since, as you recall, I testified at the last hearing on H.R. 881, on March 11, 1993. At that time, The Tobacco Institute had asked that I present my views as a scientist in regard to the report on environmental tobacco smoke (ETS) issued by the Environmental Protection Agency on January 7, 1993[1].

The Tobacco Institute has asked that I appear before you again to offer some necessary clarification to the testimony recently submitted for the record by Dr. Alfred Munzer, on behalf of the Coalition on Smoking OR Health.

All the same, the views expressed here are my own and not necessarily those of The Institute.

In his testimony, Dr. Munzer mentions especially two studies published before the release of the EPA report on ETS, but excluded from the report itself, claiming that they sustain the EPA's report conclusions. These are the studies of Stockwell et al.[2] and Brownson et al.[3], and a close look at their data as published leads to quite obvious conclusions, opposite to those reached by Dr. Munzer.

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In epidemiologic jargon, risk is reported either as relative risk (RR) or as their close approximations, the odds ratio (OR) values. Expressed values are relative to the control group, which is assigned a value of 1. Values greater than 1 suggest increased risk and values below 1 suggest decreased risk, relative to the control group. In the abstract to their paper, Stockwell at al. write:

> "The risk of lung cancer more than doubled for women who reported 40 or more smoke years of household exposure during adulthood (odds ratio [OR] = 2.4 ...) or 22 or more smoke years of exposure during childhood and adolescence (OR = 2.4 ...)... When a surrogate respondent other than the patient's husband provided information of exposure, the risk estimates were considerably lower. Conclusions: These findings suggest that long term exposure to environmental tobacco smoke increase the risk of lung cancer in women who have never smoked."[2]

What the abstract fails to indicate is that data in the paper itself show that, when surrogate respondents other than the patient's husband provided information of exposure, the risk estimates were not only considerably lower, but were actually below 1, therefore suggesting that nonsmokers exposed to ETS had a lower lung cancer risk than those who were not exposed[4].

What would a scientist do when confronted with such conflicting results? First, no conclusions would be made on that basis. Second, an investigator would try to determine which source of exposure information is credible, if any. For instance, data reported in the Stockwell et al. paper inevitably pose two

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questions. One is whether husbands, daughters, or sons are credible sources of information for ETS childhood exposure of their wives/mothers. The other is whether women with lung cancer might -- by the very questions posed to them -- be induced to find blame by amplifying or even imagining a childhood exposure to ETS presumably generated by their own parents or relatives[2].

Equally unresolved uncertainties are to be found in the Brownson et al. study, one of the largest on record[3]. According to the abstract of the paper:

> "No increased risk of lung cancer was associated with childhood passive smoke exposure. Adulthood analyses showed an increased lung cancer risk for lifetime nonsmokers with exposure of more than 40 pack-years from all household members (odds ratio [OR] = 1.3...) or from spouses only (OR = 1.3...)... Conclusions: Ours and other recent studies suggest a small but consistent increased risk of lung cancer from passive smoking. Comprehensive actions to limit smoking in public places and worksites are well-advised."[3]

Actually, data in this study reveal not only that childhood exposure was <u>not</u> associated with an excess risk of lung cancer, but that such exposure gives odds ratios that are substantially below 1, and thus reports a reduced risk for lung cancer in ETS exposed individuals. What should one make of these results, which are in direct conflict with the reports by Stockwell et al., as noted above? At the very least an impartial investigator would suspend judgment until further clarification becomes available.

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Curiously, the abstract of the Brownson et al. paper fails to note that data reported in table 2 of the paper itself are quite at odds with the author's summary conclusions about risk from ETS. To begin with, the overall analysis of risk fails to uncover an excess of risk. A small excess risk is reported only for selected categories of highest exposure, and with any other exposure level an apparent decrease of risk is reported[6]. Since overall risk is the index used in all other studies considered by the EPA report, the Brownson et al. study clearly does not support EPA's conclusions despite what its abstract suggests.

This set of results clearly conflicts with the overall conclusions of the authors. Besides, in view of the Stockwell et al. data, should Brownson et al. worry that 74% of their exposure information comes from offspring or siblings and not from the patients themselves? And what about their conclusion that smoking restrictions in workplaces are well advised, when Stockwell et al. and most other studies failed to find an association for worksite exposures to ETS, and the Brownson et al. paper itself states in its text that "there was no elevated risk of lung cancer risk associated with passive smoke exposure in the workplace..."?

In fact, the entire literature assembled by the EPA report on ETS -- both for lung cancer and respiratory conditions -- suffers contradictions similar to the Stockwell and Brownson studies, and like these studies raises more questions than it can answer. And

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I have touched here only on the superficial problems that become obvious from the reported data themselves. There are other and major fundamental problems of which I spoke in my previous testimony before you, namely how to adjust for misclassifications of exposed and unexposed individuals, for presumed background ETS exposures, and for several lung cancer and respiratory risks that are known to confound the results.

Of course, there is also the question of statistical significance. While it is true that statistical significance is a matter of consensus, it is also true that the universal consensus prescribes margins of error ±5% or lower, and frowns upon the ±10% margin that EPA insisted on using in the ETS report. In fact, EPA would certainly reject a petition for the registration of a pesticide, for instance, if it were submitted to the agency with data based on a ±10% statistical standard. Professor Dockery, whom Dr. Munzer quotes, is right when stating that the statistical significance of data "...reflects the stability, that is the uncertainty, of their effect estimate."

Indeed, by adopting a ±10% instead of the ±5% standard the EPA report aims at giving an artificial impression of the stability and certainty of the data. By this gambit the data are not changed, but their intrinsic uncertainty is fictitiously reduced. Experts may see through this machination, but also understand that its only possible purpose is to pull some wool over less sophisticated eyes.

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In a separate and less known document the EPA states:

> "Our best estimate is about 3000 deaths a year. While the true number may be higher or lower, the totality of the evidence and especially the groups receiving the highest exposure levels strongly argue that the number is greater than zero."[7]

In fact, only by artificially increasing the stability of the data and ignoring contrary evidence could the EPA make this statement, because the "totality of the evidence" is also compatible with numbers less than zero.

My purpose here is not to cast aspersions on ETS studies, but rather is intended to illustrate how contradictory and essentially uninterpretable are the results if analyzed comprehensively in a true "weight of evidence" exercise. In fact, the "weight of evidence" of which the EPA report speaks is nothing but an exercise in selective use of data, and therefore not a "weight of evidence" analysis at all.

Only by selectively choosing data that suit a preconceived policy could one arrive at the conclusions that are incorrectly represented as scientific evidence to the public and to you, members of the subcommittee, by Stockwell et al., Brownson et al., most other authors of ETS epidemiologic studies, the U.S. Surgeon General, The National Academy of Sciences, the EPA and, of course, Dr. Munzer and other advocates.

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A major justification advanced is that by now several studies have arrived at similar conclusions. However, this is true only if one eliminates all the contrary data and ignores that most studies suffer from the same defects and shortcomings. Illusory attempts have been made to increase the significance of these studies by combining their data in what is known as a meta-analysis exercise. Yet, it is intuitively difficult to improve the overall quality of conclusions by combining individual studies that are intrinsically flawed. Rotten apples could hardly make good applesauce.

In the ETS report, the EPA has no hesitation in disclosing that their analysis "is based on the a priori hypothesis ... that a positive association exists between exposure to ETS and lung cancer"[8]. On this basis, as the agency further proceeds to disregard systematically all evidence that contradicts its a priori assumption, it may as well start trying witches again.

And trying witches again it will, if Congress and our collective social culture let the agency get away with this arbitrary use of selected evidence.

There is a simple remedy: if the EPA wishes to claim that its policies are based on scientific evidence, then it should follow those rules of scientific evidence that any scientific institution or individual scientist is expected to observe.

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Indeed it is strange that at a time when scientific misconduct is hotly debated in our midst and is the burning focus of Congressional hearings, official agencies of our own government are praised and feel free and proud to operate under scientific pretensions that would bring swift reprisal to any outside scientist or institution.

Mr Chairman, Members of the Subcommittee, the real issue in front of you is not passive smoking, as you may think. In reality, you are truly deciding whether our society shall in the end become hostage to less than benevolent official powers.

REFERENCES

1. Environmental Protection Agency. Respiratory health effects of passive smoking: lung cancer and other disorders. EPA, Washington, DC, 1992

2. Stockwell, HG, et al., Environmental tobacco smoke and lung cancer risk in nonsmoking women, JNCI 84:1417-1422, 1992

3. Brownson, RC, et al., Passive smoking and lung cancer. AJPH 82:1525-1530, 1992

4. See exhibit 1 (from reference 2)

5. See exhibit 2 (from reference 3)

6. See exhibit 3 (from reference 3)

7. Letter of Dr. Erich W. Bretthauer, Assistant Administrator for Research and Development, EPA, to Mr. J.J. Tozzi. December 17, 1992

8. Reference 1, page 5-2

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EXHIBIT 1

Table 3. Effect of environmental tobacco smoke on lung cancer risk of nonsmoking women, according to source of case patient interview

Exposure history	Source of case patient interview							
	Self (n = 70)		Husband (n = 48)		Other surrogate (n = 92)		Self and husband (n = 118)	
	OR*	95% CI	OR*	95% CI	OR*	95% CI	OR*	95% CI
Exposure: yes/no								
Father	3.2	0.9-11.3	2.0	0.4-8.8	0.6	0.3-1.3	2.7	1.0-7.3
Husband	3.1	0.9-10.6	3.1	0.7-13.7	0.9	0.4-1.9	3.1	1.2-8.3
Siblings and others	—	—	—	—	—	—	4.3	1.3-14.2
Smoke-years								
Childhood/adolescence (parents and siblings)								
<18	4.3	1.1-16.7	2.4	0.4-12.8	0.6	0.2-1.9	3.6	1.2-10.8
18-21	2.4	0.5-10.6	1.6	0.2-10.5	0.6	0.2-2.0	2.1	0.6-7.2
≥22	6.5	1.7-25.5	1.4	0.2-9.6	1.6	0.5-4.8	4.4	1.4-13.5
P for trend		.04		.78		.68		.07
Adulthood (husband and others)								
<22	3.4	0.9-12.2	3.1	0.7-14.8	0.8	0.3-2.0	3.3	1.2-9.2
22-39	3.6	1.0-13.1	1.8	0.4-9.2	0.8	0.3-1.9	2.9	1.0-8.2
≥40	4.7	1.2-19.1	4.2	0.8-22.9	1.5	0.6-3.9	4.7	1.5-14.7
P for trend		.02		.05		.35		.006
All lifetime household exposure								
<22	2.0	0.5-7.6	3.2	0.7-14.9	0.6	0.3-1.6	2.5	0.9-7.2
22-39	4.4	1.3-15.6	1.0	0.2-5.6	0.6	0.2-1.4	3.1	1.1-8.6
≥40	4.1	1.1-14.8	3.5	0.7-16.7	1.3	0.7-3.6	4.0	1.4-11.3
P for trend		.01		.15		.11		.004

*OR, adjusted for age, race, and education (≤8 and >8 grades).

Source: https://www.industrydocuments.ucsf.edu/docs/tXlm0000

EXHIBIT 2

TABLE 1—Adjusted Odds Ratios (OR)[a] and 95% Confidence Intervals (CI) for the Relationship between Passive Smoke Exposure during Childhood and Lung Cancer in Women, Missouri, 1986 through 1991

	All Subjects[b]				Lifetime Nonsmokers			
Source of Exposure	No. Cases	No. Controls	OR	95% CI	No. Cases	No. Controls	OR	95% CI
All household members								
Never	430	928	1.0		323	802	1.0	
Ever	185	472	0.8	0.7, 1.1	108	364	0.8	0.6, 1.1
Cigarette pack-years								
0	430	928	1.0		323	802	1.0	
>0–15	42	129	0.7	0.5, 1.0	27	104	0.7	0.4, 1.1
>15–25	31	119	0.6	0.4, 0.9	20	91	0.6	0.4, 1.0
>25	34	117	0.7	0.4, 1.1	21	87	0.7	0.4, 1.2
Parents only								
Never	489	1021	1.0		357	877	1.0	
Ever	126	379	0.7	0.5, 0.9	74	289	0.7	0.5, 0.9
Cigarette pack-years								
0	489	1021	1.0		357	877	1.0	
>0–15	19	90	0.4	0.3, 0.7	12	70	0.5	0.2, 0.8
>15–25	27	118	0.5	0.3, 0.7	17	87	0.5	0.3, 0.9
>25	33	99	0.7	0.5, 1.1	21	74	0.8	0.5, 1.4

[a]Adjusted for age, history of previous lung disease, and active smoking (all subjects only).
[b]Includes lifetime nonsmokers and ex-smokers who had stopped at least 15 years before diagnosis or who had smoked for less than 1 pack-year.

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EXHIBIT 3

TABLE 2—Adjusted Odds Ratios (OR)[a] and 95% Confidence Intervals (CI) for the Relationship between Passive Smoke Exposure during Adulthood and Lung Cancer in Women, Missouri, 1986 through 1991

Source of Exposure	All Subjects[b]				Lifetime Nonsmokers			
	No. Cases	No. Controls	OR	95% CI	No. Cases	No. Controls	OR	95% CI
All household members								
Never	221	527	1.0		170	470	1.0	
Ever	394	873	1.0	0.8, 1.2	261	696	1.1	0.8, 1.3
Cigarette pack-years								
0	221	527	1.0		170	470	1.0	
>0–15	88	234	0.9	0.6, 1.2	56	181	0.9	0.6, 1.2
>15–40	91	261	0.8	0.6, 1.0	62	199	0.9	0.6, 1.2
>40	146	264	1.3	1.0, 1.8	107	217	1.3	1.0, 1.8
Cigarette pack-years × hours/day[c]								
0	221	527	1.0		170	470	1.0	
>0–50	90	261	0.8	0.6, 1.1	63	206	0.9	0.6, 1.2
>50–175	89	246	0.8	0.6, 1.1	58	189	0.9	0.6, 1.2
>175	124	238	1.2	0.9, 1.6	92	192	1.3	1.0, 1.8
Spouse only								
Never	287	650	1.0		213	568	1.0	
Ever	328	750	0.9	0.8, 1.1	218	598	1.0	0.8, 1.2
Cigarette pack-years								
0	287	650	1.0		213	568		
>0–15	58	166	0.7	0.5, 1.0	32	128	0.7	0.5, 1.1
>15–40	81	258	0.7	0.5, 0.9	54	200	0.7	0.5, 1.0
>40	150	266	1.2	0.9, 1.5	110	216	1.3	1.0, 1.7
Cigarette pack-years × hours/day[c]								
0	287	650	1.0		213	568	1.0	
>0–50	64	201	0.7	0.5, 0.9	41	161	0.7	0.5, 1.0
>50–175	81	237	0.7	0.5, 1.0	52	183	0.8	0.5, 1.1
>175	126	241	1.1	0.9, 1.5	94	193	1.3	1.0, 1.7

[a]Adjusted for age, history of previous lung disease, and active smoking (all subjects only).
[b]Includes lifetime nonsmokers and ex-smokers who had stopped at least 15 years before diagnosis or who had smoked for less than 1 pack-year.
[c]The product of total pack-years and average number of hours exposed per day to passive smoke in the home.

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